



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 21 1999

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**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Satish R. Shah
66 Lockwood Place
Clifton, NJ 07012

Re: Docket No. 93N-0349

Dear Mr. Shah:

I have reviewed your April 21, 1999 letter to Acting Associate Commissioner Gary Dykstra in which you submit a second request for termination of your debarment. I am writing to advise you about your request.

Any person denied special termination of debarment may obtain review of FDA's denial in the United States Court of Appeals for the District of Columbia or in the circuit in which he resides, by filing in such court (within 60 days following the date the person is notified of FDA's decision) a petition requesting that the decision be modified or set aside (see section 306(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(j))). We suggest that you consult with your attorney if you are interested in appealing FDA's opinion.

Sincerely yours,

David T. Read
Acting Director, Regulatory Policy Staff (HFD-7)
Center for Drug Evaluation and Research

93N-0349

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